NOV 17 1999

510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
Fax (717) 854-2343

P. J. Lehn Telefax (717) 849-4343

K992822

CONTACT: P. Jeffery Lehn

DATE PREPARED:

TRADE OR PROPRIETARY NAME: SEAL & PROTECT™ DENTAL VARNISH

CLASSIFICATION NAME: cavity varnish 872.3260

PREDICATE DEVICES: Prime & Bond® NT™ Universal Dental Adhesive K982394

DEVICE DESCRIPTION: SEAL & PROTECT™ DENTAL VARNISH is a nanofilled light-curing dental varnish designed to protect exposed dentine areas, both mechanically and by way of an antimicrobial agent.

INTENDED USE: SEAL & PROTECT™ DENTAL VARNISH is a protective sealant for exposed dentine. The Indications for Use are: (1) Reduction of abrasion and erosion of exposed cervical dentine; and (2) Treatment of hypersensitive cervical areas.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in SEAL & PROTECT™ DENTAL VARNISH have been used in legally marketed devices.

SEAL & PROTECT™ DENTAL VARNISH was evaluated for cytotoxicity (L929) and mutagenicity (Ames Test). The conclusions indicate that there is no evidence of any hazardous effects to the patient if the product is used as directed. The possibility of migration of constituents occurring during the application and polymerization phase cannot be absolutely ruled out. However, in light of the low volume of material applied, the low solubility in physiological liquids and the inert properties of the polymerized synthetic matrix, the amount and type of the substances temporarily released from the product must be considered as harmless.

We believe that the prior use of the components of SEAL & PROTECT™ DENTAL VARNISH in legally marketed devices, the results of biocompatibility testing, and the performance data support the safety and effectiveness of SEAL & PROTECT™ DENTAL VARNISH for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Jean Stenger
Regulatory Affairs Associate, for
P. Jeffery Lehn
Director, Corporate Compliance
and Regulatory Affairs
Dentsply International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872

Re: K992822
Trade Name: Seal & Protect™ Dental Varnish
Regulatory Class: II
Product Code: LBA
Dated: August 20, 1999
Received: August 23, 1999

Dear Ms. Stenger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA

may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 801.109)

510(K) Number: K992822

Device Name: SEAL & PROTECT™ DENTAL VARNISH

SEAL & PROTECT™ DENTAL VARNISH is a protective sealant for exposed dentine. The Indications for Use are:

- Reduction of abrasion and erosion of exposed cervical dentine
- Treatment of hypersensitive cervical areas

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____